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UNCLAS CAIRO 000090

SIPDIS

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E.O. 12958: N/A

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SUBJECT: EGYPTIAN GOVERNMENT APPROVES GENERIC COPY OF U.S.
INNOVATOR DRUG

Sensitive But Unclassified. Please protect accordingly.

1. (SBU) Representatives of Eli Lilly met with trade officer January 4 to provide information on a recently approved and marketed Egyptian generic copy of one of its innovator drugs. According to Lilly, sometime in December 2005, the Ministry of Health and Population (MOHP) gave approval to Apex Pharma to market Olapex, a copy of Eli Lilly's drug Zyprexa, which is used to treat schizophrenia and other psychoses. Eli Lilly learned of the approval only last week, when Olapex became available in Egypt's retail market, and the Olapex packages showed MOHP registration numbers 23758 and 23759, issued in December 2005.

2. (SBU) Olapex is the first marketing approval for a generic copy of a protected U.S. company product in more than a year. This move comes despite warnings from USG officials that any further marketing approvals for copies of U.S. innovator drugs -- especially Zyprexa -- would call into question the GOE's commitment to protect intellectual property rights.

3. (SBU) Eli Lilly took every available step to enforce its intellectual property rights. The company filed a patent application for Zyprexa with Egyptian officials in August 1995. Because Egypt was not obligated to begin reviewing patent applications until 2005 under WTO rules, Eli Lilly took steps to obtain interim protection for its product. Unlike many western innovator companies in a similar situation, Eli Lilly did not rely exclusively on WTO provisions that obligate Egypt to refrain from granting marketing approval for generic drugs based on the innovator company's confidential test data. Rather Eli Lilly also sought a five-year exclusive marketing right certificate for Zyprexa, which the GOE granted in August, 2001. However, Apex challenged the Eli Lilly's exclusive marketing rights on a technicality. The court ruled in Apex's favor, and Eli Lilly promptly filed an appeal, which was expected to be heard on January 17, 2006. Eli Lilly was surprised by the approval for Olapex because, according to its lawyers, Egyptian legal procedure requires that a challenged judgment is to remain unexecuted until a final ruling has been made.

4. (SBU) Eli Lilly is seeking meetings with GOE officials to request a reversal of the marketing approval or expedited review of Eli Lilly's patent application for Zyprexa. They are also asking the GOE to prevent further commercialization of the generic Olapex, and to refrain from approving any marketing requests from other Egyptian companies to make their copies of Zyprexa (Egyptian law allows up to four generics in the market for the same product). The embassy will raise this issue with all relevant GOE contacts in hopes of getting marketing approval for Olapex revoked and dissuading the MOHP from granting any more generic marketing approvals for Zyprexa or other U.S. innovator drugs.

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